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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| *Office Action Summary* | **Application No.** 10/647,796 | **Applicant(s)** GLOZMAN ET AL. | |
|---|---|---|---|
| | **Examiner** HERNG-DER DAY | **Art Unit** 2128 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16,18-39 and 41-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-39 and 41-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**1.** This communication is in response to Applicants' Response ("Response") to Office Action dated February 3, 2010, filed July 6, 2010.

**1-1.** Claims 1 and 23 have been amended. Claims 50 and 51 have been added. Claims 1-16, 18-39, and 41-51 are pending.

**1-2.** Claims 1-16, 18-39, and 41-51 have been examined and rejected.

### *Claim Objections*

**2.** Claim 51 has no end period ".". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

**3.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**4.** Claims 1-16, 18-39, and 41-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**4-1.** Claim 1 recites the limitation, "d. using *the obtained medical image* in said imaging apparatus, said image comprising said calibrated imaged anatomical structure of said patient to be operated on, planning directly on *said segmented images* of said bones to be operated on a result of the orthopedic surgical procedure to be performed on the anatomical structure to reduce said trauma present in said bone, by rearranging of *said segmented images* of said bones from

said original arrangement to simulate said result within said anatomical structure" in lines 22-28 of the claim. However, as recited in lines 11-12 of the claim, "b. obtaining and displaying in said imaging apparatus *the obtained direct medical images* of the anatomical structure along with said calibration", it does not appear that any *segmented image* of any *anatomical structure segment*, as performed in step c, is included and may be rearranged in *the obtained medical images* recited in steps b and d. Clarification of the metes and bounds, via clearer claim language, is requested. Furthermore, Claim 1 recites the limitation, "the patient" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim.

**4-2.** Claim 23 recites the limitations, "said patient" in lines 15, 16, and 26 of the claim and "said trauma" in lines 19-20 and 21-22 of the claim. There is insufficient antecedent basis for any of the recited limitations in the claim. Claim 23 also recites the limitation, "the direct *images*" in lines 20-21 of the claim which is vague and indefinite because as recited in lines 6-11 of the claim there is only one direct *image*.

**4-3.** Claim 35 recites the limitation, "the segmenting means" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

**4-4.** Claim 36 recites the limitation, "the planning means" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

**4-5.** Claim 37 recites the limitation, "the planning means" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

**4-6.** Claim 50 recites the limitation, "the simulation of the orthopedic procedure" in lines 11-12 of the claim. There is insufficient antecedent basis for this limitation in the claim.

**4-7.** Claims not specifically rejected above are rejected as being dependent on a rejected claim.

### *Claim Rejections - 35 USC § 103*

**5.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**6.** Claims 1-16, 18-39, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause et al., U.S. Patent 6,711,432 B1 issued March 23, 2004 and filed October 23, 2000, in view of Kenet et al., U.S. Patent 5,016,173 issued May 14, 1991, and further in view of Hanson et al., "OrthoDock - An Image Driven Orthopaedic Surgical Planning System", Proceedings of Twelfth Annual International Conference of the IEEE Engineering in Medicine and Biology Society, November 1990, pages 1931-1932.

**6-1.** Regarding claim 1, Krause et al. disclose a method of image manipulation in an imaging apparatus for preoperative planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, the planning being carried out on medical images that are direct images of the anatomical structure to be operated on, the method comprising inter alia:

[[a. providing a real dimension unit in said imaging apparatus, said real dimension unit defining an absolute length, thereby to provide said absolute length to appear in an image alongside said anatomical structure of the patient to be operated on to provide an image defining

a calibration of the imaged anatomical structure alongside said anatomical structure of the patient to be operated on;]]

b. obtaining and displaying in said imaging apparatus the obtained direct medical images of the anatomical structure [[along with said calibration from said real dimension unit,]] prior to said orthopedic surgical procedure[[, and using said real dimension unit calibration determining from said direct medical images an extent of trauma present in said anatomical structure]] (X-ray or fluoroscopic images of a patient's bone, column 6, lines 18-20; several regular X-ray images of the patient (which are typically taken before any surgery), column 6, lines 42-51);

c. segmenting the direct medical images of the anatomical structure to be operated on into segments in said imaging apparatus prior to said orthopedic surgical procedure, said segments being in an original arrangement (Segmentation, column 6, lines 52-57; segmented at regular intervals 120 throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54), the anatomical structure comprising bones and the segmentation comprising segmentation of the image of the bone to be operated on, to form independently movable bone part image segments to represent said trauma present in said bones (The present invention may be used in cases of multiple trauma with long bone fractures. … apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40); and

d. using the obtained medical image in said imaging apparatus, said image comprising said [[calibrated]] imaged anatomical structure of said patient to be operated on, planning [[directly on said segmented images of said bones to be operated on]] a result of the orthopedic surgical procedure to be performed on the anatomical structure to reduce said trauma present in

said bone (Figures 4-6; apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40), by rearranging of said segmented images of said bones from said original arrangement to simulate said result within said anatomical structure (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, line 14, through column 10, line 7) and producing [[calibrated]] output images comprising said bone segments rearranged to reduce said trauma, said rearranged image segments providing said preoperative planning (the planning software preferably plots the results on a 3D diagram, column 10, lines 8-17).

Krause et al. fail to expressly disclose: (1) a. providing a real dimension unit in said imaging apparatus, said real dimension unit defining an absolute length, thereby to provide said absolute length to appear in an image alongside said anatomical structure of the patient to be operated on to provide an image defining a calibration of the imaged anatomical structure alongside said anatomical structure of the patient to be operated on; and (2) and using said real dimension unit calibration determining from said direct medical images an extent of trauma present in said anatomical structure.

Kenet et al. disclose, "Once an image has been captured, calibration 314 of the image is performed to calibrate for *absolute distances* and to correct for spatial, color, or intensity distortions due to the acquisition equipment and circumstances. … For example, an image of a ruler or grid may be obtained during a calibration session, or simultaneously with the image of the surface structure of interest." (Kenet, column 10, lines 40-51). In other word, associated with

an image of a ruler in it, the image of interest becomes a *calibrated image* and is calibrated for *absolute distances*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krause et al. to incorporate the teachings of Kenet et al. because as suggested by Kenet et al., an image of a ruler obtained simultaneously with the image of the surface structure of interest would calibrate for absolute distances and to correct for spatial distortions due to the acquisition equipment and circumstances.

Krause et al. also fail to expressly disclose planning "directly on said segmented images of said bones to be operated on". Specifically, Krause et al. disclose in column 8, lines 18-21, "The result of this process is preferably a 3D software model 92 (based on 3D CAD data) of the patient's bone that is sufficient for computer-aided planning of the orthopedic surgery or other procedure." In other words, Krause et al. disclose that the planning of the orthopedic surgery is based on a 3D software model formed from direct 2D images instead of using 2D images directly.

Hanson et al. disclose an image driven orthopaedic surgical planning system: OrthoDock. Specifically, Hanson et al. disclose in page 1931, right column, paragraph 3, "Since 3d perspective projections inherently distort distance and shape, we chose to use multiple 2d slices in order to present the 3d Information."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of using 3D model images of Krause et al. to incorporate the teachings of Hanson et al. of using 2D images because, as suggested by Hanson et al., 3d

perspective projections inherently distort distance and shape and, therefore, multiple 2d slices are used in order to present the 3d Information.

**6-2.** Regarding claim 2, Krause et al. further disclose comprising dynamic rendering of medical device from pre defined members, the method allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, lines 25-28).

**6-3.** Regarding claim 3, Krause et al. further disclose wherein said medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

**6-4.** Regarding claim 4, Krause et al. further disclose wherein said medical images are a combination of plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

**6-5.** Regarding claim 5, Krause et al. further disclose wherein said medical images comprise a plurality of views of said anatomical structure (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

**6-6.** Regarding claim 6, Krause et al. further disclose wherein the obtaining step comprises transforming of said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

**6-7.** Regarding claim 7, Krause et al. further disclose wherein said obtaining includes composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

**6-8.** Regarding claim 8, Kenet et al. further disclose wherein the obtaining step comprises calibrating of images (calibration 314 of the image is performed, column 10, lines 40-44).

**6-9.** Regarding claim 9, Krause et al. further disclose wherein said calibrating comprises registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

**6-10.** Regarding claim 10, Krause et al. further disclose wherein said calibrating comprises dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

**6-11.** Regarding claim 11, Kenet et al. further disclose wherein said calibrating comprises image enhancements comprising brightness and contrast adjustments, and edge detection (to correct for spatial, color, or intensity distortions, column 10, lines 40-44).

**6-12.** Regarding claim 12, Krause et al. further disclose wherein the segmenting step is performed in at least one of a group of ways, comprising: manual performance by a medical expert, automatic performance, wherein the anatomical structure segments are segmented according to predefined rules, and semi-automatic performance, wherein the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

**6-13.** Regarding claim 13, Krause et al. further disclose wherein said rearranging comprises simulating different positioning of said image anatomical structure segments (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, lines 23-67).

**6-14.** Regarding claim 14, Krause et al. further disclose wherein said different positioning of said image anatomical structure segments relates to reducing of said trauma during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

**6-15.** Regarding claim 15, Krause et al. further disclose wherein said different positioning of said image anatomical structure segments relates to pre designed osteotomy treatments (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

**6-16.** Regarding claim 16, Krause et al. further disclose comprising inserting implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, lines 25-28).

**6-17.** Regarding claim 18, Krause et al. further disclose comprising a step of choosing a plurality of fixation elements from a predefined database (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

**6-18.** Regarding claim 19, Krause et al. further disclose comprising rules for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

**6-19.** Regarding claim 20, Krause et al. further disclose wherein said planning comprises producing and storing the output images and planning reports of a plurality of alternatives of said steps of segmenting and planning, for the purpose that the best alternative for medical treatment is selected from said alternatives; said planning report comprising part definition of said

calibrated artificial elements selected for the treatment as well as patient information (determine the appropriate locations, column 10, lines 8-17); said planning report comprising part definition of calibrated artificial elements selected for the treatment as well as patient information (preliminary surgical plan, column 10, lines 46-62).

**6-20.** Regarding claim 21, Krause et al. further disclose additionally comprising a step of providing hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

**6-21.** Regarding claim 22, Krause et al. further disclose additionally comprising a step of communicating said output images and said planning reports to a plurality of remote users (to remotely access other experts, column 2, lines 48-58).

**6-22.** Regarding claim 23, Krause et al. disclose an apparatus for pre-planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, said preplanning carried out directly on medical images taken of the anatomical structure to be the subject of the surgical procedure, the apparatus comprising;

[[a. a real dimension unit defining an absolute length, to provide said absolute length to appear in an direct medical image of said anatomical structure, said real dimension unit appearing alongside said anatomical structure to be the subject of the surgical procedure to provide a calibrated direct medical image of said anatomical structure;]]

b. a segmenting unit for defining and marking anatomical structure segments in an original arrangement in the direct medical image of the anatomical structure to be the subject of the surgical procedure (Segmentation, column 6, lines 52-57; segmented at regular intervals 120

throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54), the anatomical structure comprising bones of said patient and the image segments being direct image segments of said bones of said patient, said direct image segments being independently movable (The present invention may be used in cases of multiple trauma with long bone fractures. … apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40);

c. a planning unit for planning a result of said orthopedic surgical procedure to be performed on the anatomical structure to minimize said trauma, [[the direct images having said real dimension unit calibration to estimate an extent of said trauma]] (Figures 4-6; apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40), the planning unit comprising a rearranger for rearranging of said [[direct]] image anatomical structure segments from said original arrangement to simulate said result within said anatomical structure (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, line 14, through column 10, line 7) thereby to produce [[calibrated]] output images, the [[calibrated]] output images comprising said direct image anatomical structure bone segments of said patient being rearranged (the planning software preferably plots the results on a 3D diagram, column 10, lines 8-17);

d. a memory for storing said medical images and a desired result (a planning computer … has developed a detailed preliminary surgical plan, column 11, lines 15-19); and,

e. a display for displaying said [[calibrated]] medical images and said output images (The surgeon can preferably view the 3D computer simulation or other plan of the surgery, column 11, lines 19-27).

Krause et al. fail to expressly disclose: (1) a. a real dimension unit defining an absolute length, to provide said absolute length to appear in an direct medical image of said anatomical structure, said real dimension unit appearing alongside said anatomical structure to be the subject of the surgical procedure to provide a calibrated direct medical image of said anatomical structure; and (2) the direct images having said real dimension unit calibration to estimate an extent of said trauma.

Kenet et al. disclose, "Once an image has been captured, calibration 314 of the image is performed to calibrate for *absolute distances* and to correct for spatial, color, or intensity distortions due to the acquisition equipment and circumstances. … For example, an image of a ruler or grid may be obtained during a calibration session, or simultaneously with the image of the surface structure of interest." (Kenet, column 10, lines 40-51). In other word, associated with an image of a ruler in it, the image of interest becomes a *calibrated image* and is calibrated for *absolute distances*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krause et al. to incorporate the teachings of Kenet et al. because as suggested by Kenet et al., an image of a ruler obtained simultaneously with the image of the surface structure of interest would calibrate for absolute distances and to correct for spatial distortions due to the acquisition equipment and circumstances.

Krause et al. also fail to expressly disclose rearranging of said "direct image anatomical structure segments". Specifically, Krause et al. disclose in column 8, lines 18-21, "The result of this process is preferably a 3D software model 92 (based on 3D CAD data) of the patient's bone that is sufficient for computer-aided planning of the orthopedic surgery or other procedure." In other words, Krause et al. disclose that the planning of the orthopedic surgery is based on a 3D software model formed from direct 2D images instead of using 2D images directly.

Hanson et al. disclose an image driven orthopaedic surgical planning system: OrthoDock. Specifically, Hanson et al. disclose in page 1931, right column, paragraph 3, "Since 3d perspective projections inherently distort distance and shape, we chose to use multiple 2d slices in order to present the 3d Information."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of using 3D model images of Krause et al. to incorporate the teachings of Hanson et al. of using 2D images because, as suggested by Hanson et al., 3d perspective projections inherently distort distance and shape and, therefore, multiple 2d slices are used in order to present the 3d Information.

**6-23.** Regarding claim 24, Krause et al. further disclose comprising means for dynamic rendering of medical device from pre defined members, allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, lines 25-28).

**6-24.** Regarding claim 25, Krause et al. further disclose wherein the medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

**6-25.** Regarding claim 26, Krause et al. further disclose wherein the medical images are combination of a plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

**6-26.** Regarding claim 27, Krause et al. further disclose wherein the medical images comprise a plurality of views of the same anatomical structures (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

**6-27.** Regarding claim 28, Krause et al. further disclose additionally comprising means for transforming said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

**6-28.** Regarding claim 29, Krause et al. further disclose additionally comprising means for composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

**6-29.** Regarding claim 30, Kenet et al. further disclose additionally comprising calibration means for images (calibration 314 of the image is performed, column 10, lines 40-44).

**6-30.** Regarding claim 31, Krause et al. further disclose wherein the calibration means are also utilized for registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

**6-31.** Regarding claim 32, Krause et al. further disclose wherein the calibration means are also utilized for dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

**6-32.** Regarding claim 33, Kenet et al. further disclose wherein the calibration means are also utilized for image enhancements (to calibrate for absolute distances and to correct for spatial,

color, or intensity distortions due to the acquisition equipment and circumstances, column 10, line 40-44).

**6-33.** Regarding claim 34, Kenet et al. further disclose wherein the calibration means are also utilized for correction of image distortions (to correct for spatial, color, or intensity distortions, column 10, lines 40-44).

**6-34.** Regarding claim 35, Krause et al. further disclose wherein the segmenting means are manually operated by a medical expert or wherein the segmenting means are automatically operated according to predefined rules, or wherein the segmenting means are operated semi-automatically in the manner that the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

**6-35.** Regarding claim 36, Krause et al. further disclose wherein the planning means are additionally utilized for simulating different positioning of said anatomical structure segments (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, lines 23-67).

**6-36.** Regarding claim 37, Krause et al. further disclose wherein the planning means are utilized for simulating reduction of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

**6-37.** Regarding claim 38, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments for deformed

anatomical structures (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

**6-38.** Regarding claim 39, Krause et al. further disclose comprising implants, for superposition in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, lines 25-28).

**6-39.** Regarding claim 41, Krause et al. further disclose comprising a predefined database comprising predefined sets of fixation elements (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

**6-40.** Regarding claim 42, Krause et al. further disclose comprising means for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

**6-41.** Regarding claim 43, Krause et al. further disclose additionally comprising a means for producing and storing planning reports of plurality of alternatives, for the purpose that the best alternative for medical treatment is selected from said alternatives (determine the appropriate locations, column 10, lines 8-17), said planning reports comprising part definition of calibrated artificial elements selected for the medical treatment and patient information (preliminary surgical plan, column 10, lines 46-62).

**6-42.** Regarding claim 44, Krause et al. further disclose additionally comprising a hard copy producer configured to produce hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

**6-43.** Regarding claim 45, Krause et al. further disclose additionally comprising a communication device for communicating said output images and said planning reports to remote users (to remotely access other experts, column 2, lines 48-58).

**6-44.** Regarding claim 46, Kenet et al. further disclose wherein said real dimension unit comprises an object of a known length (an image of a ruler … may be obtained … simultaneously with the image of the surface structure of interest, column 10, lines 49-51).

**6-45.** Regarding claim 47, Krause et al. further disclose wherein said medical images of the anatomical structure are imaged on an imager remote from the location of the orthopedic surgical procedure (several regular X-ray images of the patient (which are typically taken before any surgery), column 6, lines 42-51).

**6-46.** Regarding claim 48, Krause et al. further disclose wherein said displayed image comprises a final image for the orthopedic surgical procedure (a planning computer … has developed a detailed preliminary surgical plan, … The surgical plan may be sent to the surgeon using various media types including: still images and illustrations, column 11, lines 15-25).

**6-47.** Regarding claim 49, Krause et al. further disclose wherein said obtained output images further comprise, at least one feature selected from the group consisting of: a plurality of calibrated organs; a plurality of calibrated artificial elements; and at least one superposition of said calibrated artificial elements on said calibrated organs or organ segments (Figure 4).

**6-48.** Regarding claim 50, Krause et al. disclose a method of pre-operative planning for an orthopedic procedure on a patient anatomical structure, the method using a medical imaging device, the method comprising:

[[placing a scale next to said patient anatomical structure such that said anatomical structure can be imaged with said scale;]]

obtaining a direct medical image of said patient anatomical structure [[including said scale]], using said medical imaging device (X-ray or fluoroscopic images of a patient's bone, column 6, lines 18-20; several regular X-ray images of the patient (which are typically taken before any surgery), column 6, lines 42-51);

segmenting said direct medical image into direct medical image segments, each segment being of a part of said anatomical structure which is separately rearrangeable in said orthopedic procedure (Segmentation, column 6, lines 52-57; segmented at regular intervals 120 throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54); and

rearranging said [[direct]] medical image segments to carry out the simulation of the orthopedic procedure (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, line 14, through column 10, line 7; apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

Krause et al. fail to expressly disclose placing a scale next to said patient anatomical structure such that said anatomical structure has been imaged with said scale.

Kenet et al. disclose, "Once an image has been captured, calibration 314 of the image is performed to calibrate for *absolute distances* and to correct for spatial, color, or intensity distortions due to the acquisition equipment and circumstances. … For example, an image of a

ruler or grid may be obtained during a calibration session, or simultaneously with the image of the surface structure of interest." (Kenet, column 10, lines 40-51). In other word, associated with an image of a ruler in it, the image of interest becomes a *calibrated image* and is calibrated for *absolute distances*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krause et al. to incorporate the teachings of Kenet et al. because as suggested by Kenet et al., an image of a ruler obtained simultaneously with the image of the surface structure of interest would calibrate for absolute distances and to correct for spatial distortions due to the acquisition equipment and circumstances.

Krause et al. also fail to expressly disclose rearranging said "medical image segments". Specifically, Krause et al. disclose in column 8, lines 18-21, "The result of this process is preferably a 3D software model 92 (based on 3D CAD data) of the patient's bone that is sufficient for computer-aided planning of the orthopedic surgery or other procedure." In other words, Krause et al. disclose that the planning of the orthopedic surgery is based on a 3D software model formed from direct 2D images instead of using 2D images directly.

Hanson et al. disclose an image driven orthopaedic surgical planning system: OrthoDock. Specifically, Hanson et al. disclose in page 1931, right column, paragraph 3, "Since 3d perspective projections inherently distort distance and shape, we chose to use multiple 2d slices in order to present the 3d Information."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of using 3D model images of Krause et al. to incorporate the teachings of Hanson et al. of using 2D images because, as suggested by Hanson et al., 3d

perspective projections inherently distort distance and shape and, therefore, multiple 2d slices are used in order to present the 3d Information.

**6-49.** Regarding claim 51, Krause et al. further disclose wherein said segmenting comprises dividing said direct medical image such that said segments comprises a part of said anatomical structure which is separately rearrangeable in said orthopedic procedure (Segmentation, column 6, lines 52-57; segmented at regular intervals 120 throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54).

***Applicants' Arguments***

**7.** Applicants argue the following:

**7-1.** 35 U.S.C. § 112 Rejections

(1) "The claim has been amended to specify that the anatomical structure is imaged, that the image is a direct image of the anatomical structure and that it is the direct image of the anatomical structure that is segmented and rearranged." (Page 11, paragraph 3, Response)

**7-2.** 35 U.S.C. § 103 Rejections

(2) "The present embodiments however actually teach using the scaled direct medical images themselves to simulate the orthopedic procedure. There is no teaching in either Kennet or Krause or their combination to segment the direct images of the patient's bone structure and simulate the orthopedic procedure by rearranging these direct image segments." (Page 12, the last paragraph, through page 13, paragraph 1, Response)

(3) "All the prior art of record teaches is that direct medical images are scaled, but that a three-dimensional model is segmented and rearranged to carry out the simulation of the orthopedic procedure." (Page 13, paragraph 5, Response)

***Response to Arguments***

**8.** Applicants' arguments have been fully considered.

**8-1.** Applicants' argument (1) is not persuasive. The limitation in step d recites "using *the obtained medical image*" planning a result. However, "*the obtained direct medical images*" obtained in step b do not appear comprising any *segmented image* for planning.

**8-2.** Applicants' arguments (2) and (3) are moot in view of the new ground(s) of rejection. The rejections of claims 1-16, 18-39, and 41-49 under 35 U.S.C. 103(a) in Office Action dated February 3, 2010, have been withdrawn.

***Conclusion***

**9.** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kamini S Shah/

Supervisory Patent Examiner, Art Unit 2128

/Herng-der Day/
Examiner, Art Unit 2128
August 24, 2010